135 ~~49~~. (Amended) A monoclonal antibody comprising a binding site which binds to osteoclastogenesis inhibitory factor protein, said protein characterized by:

(a) molecular weights as determined by SDS-polyacrylamide gel electrophoresis (SDS-PAGE) of approximately 60kD under reducing conditions, and

approximately 60kD (a monomer) and 120 kD (a homodimer) under non-reducing conditions;

(b) high affinity to cation-exchange resins and heparin derivatives;

(c) inhibitory activity for osteoclast differentiation and/or maturation, wherein said activity is decreased by heating said protein at about 70°C for about 10 min. or at about 56°C for about 30 min., and wherein said activity is lost by heating at about 90°C for about 10 min.; and

(d) an internal amino acid sequence as provided in SEQ. ID NOS. 1, 2, or 3:

wherein said monoclonal antibody is produced by a hybridoma selected from the group consisting of A1G5 having Accession No. FERM BP-7441, D2F4 having Accession No. FERM BP-7442, and E3H8 having Accession No. FERM BP-7443 ~~binding sites~~.

## REMARKS

Claims 37-49 are pending. Claim 49 has been amended to correct a typographical error. Support for this amendment can be found throughout the specification and claims as originally filed, particularly on page 80, line 1 to page 85 line 1. No new matter has been introduced by this amendment.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in the documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account Number 50-1824, referencing docket number 16991.005. Applicants likewise authorize a charge to Deposit Account Number 50-1824 for any other fees related to the present application that are not otherwise provided for in the accompanying documents.

1. Claims 37-49 are pending and being acted upon.

2. Objection to Disclosure

The disclosure is objected to because of the use of "MICROTITER," "IMMUNOPURE," "SEPHAROSE," "PBLUESCRIPT," "QIAEX," "READY-TO-GO," "PROBLOTT," "OPTI-MEM," and "ZAP EXPRESS" without capitalization and accompaniment by the ™ or ® symbol. Office action dated April 9, 2002 at page 2. As indicated in a previous response, Applicants will file a substitute specification upon indication of allowable subject matter.

3-5. 35 U.S.C. 112, First Paragraph Rejections

Claims 37-49 stand rejected under 35 U.S.C. §112, 1st paragraph as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Office action dated April 9, 2002 at page 2. The Examiner acknowledges that Applicants' Deposit Declaration, filed on January 8, 2002 indicates that the hybridomas designated FERM BP-7441, FERM BP-7442, and FERM BP-7443 have been deposited under the provisions of the Budapest Treaty and that all restrictions on public availability will be irrevocably removed upon the granting of a patent based on the instant application. However, the Examiner has indicated that Applicants must further declare that said hybridoma will be maintained in a public depository for 30 years after the date of deposit, or 5 years after the last request for a sample, or for the enforceable life of the patent, whichever is longer. Office action dated April 9, 2002 at pages 2-3.

Applicants have submitted a document that they believe fulfills the Examiner's request. Applicants have amended the specification in accordance therewith. No new matter is thereby introduced. In light of Applicants' amendment, Applicants respectfully request that the Examiner now withdraw the rejection.



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6-7. Rejections Under 35 U.S.C. 112, First Paragraph.

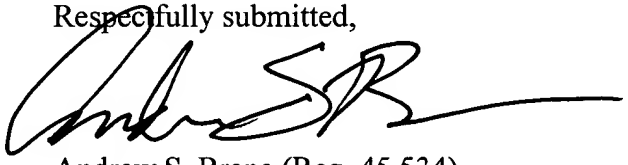
Claim 49 stands rejected under 35 U.S.C. §112, 1st paragraph because the specification allegedly does not contain a written description of the claimed invention, in that the disclosure does not reasonable convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. Office action dated April 9, 2002 at page 3.

Applicants have amended "AIG5" in claim 49 to correctly read "A1G5." As noted by the Examiner, this amendment obviates the rejection. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

**Conclusion**

In view of the above, the presently pending claims in the application are believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is invited to contact the undersigned at (202) 942-5085 with respect to any unresolved issues remaining in this application.

Respectfully submitted,



Andrew S. Brenc (Reg. 45,534)
Danielle M. Edwards, Law Clerk (Reg. 51,645)

Date: October 8, 2002

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**Marked Up Claims**

49. (Amended) A monoclonal antibody comprising a binding site which binds to osteoclastogenesis inhibitory factor protein, said protein characterized by:

(a) molecular weights as determined by SDS-polyacrylamide gel electrophoresis (SDS-PAGE) of approximately 60kD under reducing conditions, and

approximately 60kD (a monomer) and 120 kD (a homodimer) under non-reducing conditions;

(b) high affinity to cation-exchange resins and heparin derivatives;

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(d) an internal amino acid sequence as provided in SEQ. ID NOS. 1, 2, or 3:

wherein said monoclonal antibody is produced by a hybridoma selected from the group consisting of [AIG5] A1G5 having Accession No. FERM BP-7441, D2F4 having Accession No. FERM BP-7442, and E3H8 having Accession No. FERM BP-7443 binding sites.



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